INSTITUTIONAL REVIEW BOARD (IRB)

GUIDELINES AND APPLICATION MATERIALS FOR RESEARCH

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DEPARTMENT OF HEALTH AND HOSPITALS
INSTITUTIONAL REVIEW BOARD(IRB)
GUIDELINES AND APPLICATION MATERIALS FOR RESEARCH

All research proposals involving clients/patients, staff or services in programs/facilities operated or funded by the Department must be reviewed and approved by the DHH Institutional Review Board (hereafter referred to as the DHH IRB). The purpose of the review process is to assure that all research procedures include safeguards to protect clients' rights and welfare and are ethically and professionally sound. The guidelines were adapted from the Federal Policy for the Protection of Human Subjects (45 CFR 46) of the National Institutes of Health Office for Protection from Research Risks (NIH/OPRR).

The DHH IRB's review determines if proposals satisfy all approval criteria. Desired characteristics of research proposals are enumerated on the Proposal Review Form see Attachment 1 on page six (6). Researchers may use that Form as a convenient check list for ensuring that their proposals include all of the essential elements.

Following review of the proposal, the IRB, by majority vote, recommends one of three categories: 1) Full Approval, 2) Disapproved with stipulation(s), and 3)Disapproved. Those proposals receiving Full Approval are forwarded to the Secretary or his/her designee for authorization. Disapproved with Stipulation(s) indicates that minor modifications to research procedures are needed before the proposal can be fully approved. The researcher must submit the recommended modifications to the Chairperson of the IRB within 30 days of notification in order for the proposal to be reclassified and fully approved.

The Secretary or designee will notify the researcher in writing of the IRB's decision to approve or disapprove the proposed research. If the proposal is not approved, the letter will indicate reasons for disapproval and give the researcher an opportunity to respond in writing to the IRB. However, there are no appeals for research proposals disapproved because of ethical shortcomings or potential harm to subjects. Research cannot commence at the facility/program until written approval is received from the Secretary or his/her designee or, in cases of expedited review, from the Chairperson of the IRB.

Researchers are invited and encouraged to attend Board meetings at which their proposal is being reviewed, but his/her presence is not mandatory for full approval of the proposal. If the researcher cannot be present at the meeting, he/she should be available at an indicated phone number during the time of the review proceedings so that he/she can be contacted if necessary.

Research involving no more than minimal risk (e.g., studies utilizing case record data) may qualify for expedited review by the Chairperson of the DHH IRB. So may proposals which have been approved by an internal or duly constituted external IRB.

The Application Process

The following are the required documents for application. An application is not complete until all of the following documents have been received by the DHH IRB Chairperson.

1) Research Application completed and signed by the indicated persons.

2) Research Proposal Abstract or Prospectus, a typewritten manuscript which must describe:

   a) The purpose of the research; that is, the background (review of relevant literature), objectives, rationale, significance, and reasons for conducting the research.

   b) The research plan; that is, the basic research design and data collection procedures to be utilized; a description of all questionnaires, apparatuses, or devices; the number of subjects to be involved and how they will be approached and selected for participation in the research; and the planned data analysis.

3) Informed Consent documents (discussed under requirements for informed consent), unless the research involves only extraction of data from clients' clinical records.

4) Copies of any questionnaires, survey instruments, or other data collection devices, unless these are in common use and have widespread familiarity.

5) Letter or Memorandum of endorsement from the manager of each facility/program where the research is to be conducted and from appropriate administrators in that program office. The manager's letter should include that he/she has reviewed the proposal and finds that it is feasible to conduct the research project at the facility, that the research procedures will be minimally disruptive of facility operations, and that he/she will appoint a staff member to coordinate the researcher's activities at the facility during the course of the project. Additional approval moving up the chain-of-command in the

Program Office must be obtained before the proposal is sent to the DHH IRB. Forms for obtaining necessary approval are included in this package for the applicant's and agency's convenience.

University or college students must also provide documentation that research will be supervised by both a faculty member and a DHH employee and has been approved by the university or college IRB. In addition, the student should also ascertain that the DHH IRB has on file a copy of the university's or college's research policies.

Researchers should contact the facility/program manager early in the planning stages to gain his/her interest and support in the project and initiate a working relationship.

Send all application materials and inquiries to:

DHH Institutional Review Board
Post Office Box 2870
628 North 4th Street, 2nd Floor
Baton Rouge, LA 70802-2870
Phone: 225-342-3807

The DHH IRB meets quarterly at the dates indicated below, unless otherwise specified by the Chairperson. Researchers should contact the Chairperson to confirm the review dates and the status of applications. All application materials must be received by the Chairperson no later than two weeks in advance of the following review dates:

First Thursdays in February, May, August, and November.

Requirements for Informed Consent

General Requirements:

A written consent form must be signed by each subject in all research involving direct participation of client or staff. Although informed consent is not required for research involving only extraction of data from clients' clinical records, other procedures for the maintenance of confidentiality of data do apply. In general, the extensiveness of the consent form should be commensurate with the degree of risk to which the subject is exposed. (See Attachment 2, page seven [7] for a sample informed consent form.)

The consent form must be written in clear, simple language [at approximately the sixth-grade level] which can be understood by the clients/subjects.

Elements of Informed Consent Must Include:

1) An explanation of the purpose for the research, the procedures involved, the expected duration of client/staff participation, and a stipulation that the project is experimental in nature and not a regular part of the treatment program at the facility.

2) A statement that participation is completely voluntary and that refusing to participate in the project in no way affects the services the client/staff is receiving or will receive; nor does it affect the client/staff's status in the program. In addition, client/staff must be informed that they may cease participation at any time without personal consequence.

3) A full description of both the possible benefits of the research and the possible risks or discomforts related to participation, if any.

4) An explanation of how the privacy of the client and the confidentiality of the information will be assured, including how the information will be used, by whom, and that his/her name will not be used in reporting the results of the research.

5) An assurance that significant new findings developed during the course of the research which may relate to the client/staff's willingness to participate will be provided promptly to the client/staff.

6) An offer to the client/staff to answer any questions that may arise regarding the nature of the research and the client's participation.

7) Signatures of the client/staff, parent or guardian if necessary, the researcher, a witness, and a date.

The procedures for informed consent must be reviewed by the DHH IRB and documented by inclusion of the consent form with the application. A sample consent form, which would meet IRB requirements if properly completed, is included below.

The DHH IRB may appoint a consent auditor to observe the consent process for some projects, particularly those involving minors, special populations, or special procedures. The consent auditor is authorized to suspend research activities pending a report to the DHH IRB in the event a suspected violation of patient rights is observed. The researcher is duly informed of this action and is given the opportunity to respond. The IRB chair or a designee will decide whether to require modification in the consent procedures and/or research protocol.

After the research is completed, it is the responsibility of the researcher to remove any confusion, misinformation, stress, discomfort, or concerns that may remain for the client/staff as a result of their participation.

Informed Consent for Minors, Special Populations, and Special Procedures: (See 45 CFR 46, Protection of Human Subjects, Subparts B, C, and D):

When the research subjects are minors or functionally incompetent to provide informed consent, participation must be approved by client/staff's legal representatives (e.g., parents, guardians, family members). The consent form should contain the usual information required for informed consent. In addition, the client/staff, if capable, must verbally agree to participate.

In research involving drugs, the same informed consent procedures are followed, but, in addition, the consent form should indicate the type and dosage of the drugs to be given and the main side effects. The IRB may require other information.

Waiver of Written, Signed Informed Consent:

Some of the elements of informed consent may be waived by the Committee if there is adequate justification, documented by the investigator, which indicates that one or more of the following is applicable.

1) Research or demonstration project is conducted by or subject to approval of state government officials to study or evaluate public impact of benefits or services provided or funded by the Department.

2) Research deals with improving procedures for obtaining benefits or services and/or suggesting appropriate alternatives to such procedures.

3) Research will not involve identifying individual recipients of benefits/services.

The DHH IRB may waive the requirement for the investigator to obtain a signed consent form from some or all of the subjects if it finds either:

1) That the only record linking the subject and research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. In such cases, each subject will be asked if he/she wants documentation linking him/her with the research, and the subject's wish shall govern;

2) That the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation is waived, the IRB may require the investigator to provide subjects with a written explanation of the research and the waiver.

Requirements of Periodic Progress Reporting

The Committee will periodically request progress reports on the current status of research projects. It is also the responsibility of the researcher to report immediately to the DHH IRB and Facility Manager any unanticipated adverse reactions/events which occur as a result of the research activities. Significant changes in the research protocol must be reported to the DHH IRB and approved prior to implementation.

A final report of the research findings must be submitted to the DHH IRB and to appropriate persons in the Program Office upon completion of the research. Failure to submit this report will negatively impact future research requests. A presentation of the results of the project to the facility or program staff is strongly encouraged.

Attachment 1

DHH INSTITUTIONAL REVIEW BOARD--PROPOSAL REVIEW FORM

[To be filled out by IRB Members]

Title of Research: _____

Principal Investigator: _____

REQUIRED CHARACTERISTICS
Indicate whether met (+) or not met (-)

_____1. Research design is appropriately developed to benefit participants and/or to improve service system.

_____2. The proposal indicates the project meets the minimum standards for human subject research.

_____3 . Qualifications of the principal investigator demonstrate the requisite research expertise.

_____4. Proposal incorporates procedures designed to minimize the risk to the individual participants.

_____5. Research design minimizes possible disruptive effects of project on organizational operation.

_____6. Research design complies with accepted ethical standards.

_____7. Individuals participate voluntarily and prior to giving their consent are provided with a description of the expected benefits, potential discomforts and risks, alternative services (if applicable), and full explanation of procedures to be followed.

_____8. Proposal addresses participants' rights to privacy and confidentiality.

_____9. Safeguards are established to deal with any potentially harmful effects that may occur in the course of the research activity.

_____10. Research proposal is recommended by the line manager and has been approved by appropriate administrators.

IRB Member _____ **Date** _____

_____ **Approved** _____**Disapproved with stipulation(s)** _____ **Not Approved**

Required Changes:

Attachment 2

DEPARTMENT OF HEALTH AND HOSPITALS(DHH) INSTITUTIONAL REVIEW BOARD(IRB)

SAMPLE INFORMED CONSENT FORM

All Sections Must Be Completed and Fully Explained To Subject.
[Responses may be attached]

1. Project Title:
2. Research Location(s):
3. Principal Investigator:
   Address:
   Phone Number:
4. Description Of Research Activities (purpose, duration, use of drugs, other applicable components; include here: statement that study is experimental and not part of usual services):
5. Benefits To Subjects:
6. Risks To Subjects:
7. Alternatives To Participation In Research:
8. Subject Removal Criteria:
9. Subject's Right To Refuse To Participate Or To Withdraw: I understand that participation in this study is voluntary and that I may refuse to participate or withdraw at any time without penalty, especially as concerns my status in or services received from this program, either now or in the future. I will also be informed if the research leads to important things which may change my decision to participate.
10. Subject's Right To Privacy: I understand that my privacy will be protected and that neither my name nor any information identifying me will be used under any circumstances.
11. Release Of Information: I understand that this form does not authorize the release of any identifying information to any party under any circumstances; nor does it authorize the release of information from my case record.
12. Publication/Distribution of Findings: I understand that the results of this research may be published or otherwise distributed but that the results will not contain any identifying information.
13. Assurances/Signatures: This study has been discussed with me. I have been able to ask questions, and those questions have been answered to my satisfaction. I understand that I can ask other questions of the researcher(s) at any time. I have also been informed that if I have concerns about rights of human subjects of research, I can call the Bureau of Policy Research and Health Systems Analysis at 225-342-3807. I agree with the terms of this consent form and have been given a copy

_____ _____
Signature of Subject Date Signature of Witness Date

_____
Signature of Investigator Date

Reader Attests:
The subject has informed me that she/he is unable to read. I hereby certify that I have read this consent form to the subject and have explained that by signing above, she/he agrees to participate.

_____
Signature of Reader Date

Children and/or Subjects Unable To Give Informed Consent:
The subject is _____, a child or person unable to give informed consent, and I certify that I am the subject's legal guardian and do give my consent for his/her participation.

_____ _____
Legal Guardian's Name/Signature Date Subject's Name Age

_____
Subject's Signature Date

Attachment 3

Facility/Program Authorization Form

DATE:

M E M O R A N D U M

TO: _____
Chairperson, DHH Institutional Review Board

FROM: _____
Facility/Program Manager's printed name and signature required

_____ _____
Facility/Program Name Location

RE: _____

_____
Title of Research Proposal

I have reviewed the above-entitled research proposal. The research procedures appear to be minimally disruptive to clinical and facility operations. I agree to provide the necessary support requested in the application and hereby designate a staff member, _____, who will be responsible for monitoring these research activities.
(name and signature required)

I understand that any modifications to the research protocol must be approved by the DHH IRB prior to implementation. I agree to suspend research activities and to report to the DHH IRB any unauthorized research modifications or instances in which client rights appear to be violated.

I understand that the researcher is not authorized to begin research activities at this facility until written authorization from the Secretary or designee is received.

Send c/o:

Chairperson
Institutional Review Board
628 North 4th Street, 2nd Floor
Baton Rouge, Louisiana 70802
Phone: (225) 342-3807

Attachment 4

APPLICATION TO CONDUCT RESEARCH IN DHH OPERATED OR FUNDED FACILITY/PROGRAM

This application must accompany all research proposals submitted for review by the DHH IRB. All items must be either completed or indicated as not applicable.

1. Title of Research Proposal:

2. Principal Investigator:
   Address:
   Phone:
   Affiliations:
   Education/Qualifications (attach vita):

3. Co-Investigators:
   Address(es):
   Phone(s):
   Affiliations and Education/Qualifications (attach vitae if applicable):

4. University Faculty Sponsor (complete if researcher is a student):

5. Approximate dates research is to be conducted:(ex. xx/xx/xxxx)
   Begin date: _____ End date: _____

6. DHH Facilities and locations where research is to be conducted:
   a.
   b.
   c.
   d.

7. Requirements of research project from DHH:
   a. number of subjects/time required:
   b. program support personnel/space/equipment:
   c. other needs(specify):

8. Attach Abstract of the Research Proposal.

9. Attach brief description of potential benefits of this research.

10. Attach brief description of potential risks of physical or psychological harm, or discomfort to participant (if any).

11. Attach brief description of procedures to be used to establish informed consent of research participants (if applicable). Attach Informed Consent Form immediately after this page. If a waiver of any aspects of informed consent is requested, a statement of justification is required here.

12. Will client personal-identifying information (e.g., name, address, Medicaid recipient number, Social Security Number, phone number) be collected in the course of this research project?(yes, no): If **yes**, attach explanation why it is necessary to identify the clients.

13.Attach brief description of procedures to be used to protect clients' privacy and to maintain the confidentiality of data.

RESEARCHER'S PLEDGE

I am applying to conduct the research project entitled above at the indicated DHH facilities/programs. I agree to conduct this research in an ethical and responsible manner and as stipulated by the proposal and this application. I agree to secure the approval of the DHH IRB for any modifications to the research protocol. I understand that I have an ethical and legal responsibility not to divulge the identity of any clients or any information about them as identifiable individuals, nor will the final compilation of results of this project contain any client identification information. As soon as the project is complete, all client-identifying information collected will be destroyed. I agree to keep the DHH IRB informed periodically of the progress of the project, and I will submit a report of the final results to the IRB and facilities/programs involved.

Signature of principal investigator Date

Signature of Co-Investigator(s) Date

Attachment 4

UNIVERSITY FACULTY SPONSORSHIP

(Complete For Student Researchers Only)

I have reviewed this research application and proposal and find that the research design and planned data analyses are appropriate to the research objectives and that there are safeguards to protect the rights and welfare of the research participants. I hereby assume responsibility for supervision of this/these students' research activities during the course of the project.

_____ _____

Signature of faculty member Date

_____ _____

College/University Location

Attach University IRB Approval after this page.

Attachment 5

PROGRAM OFFICE ADMINISTRATIVE APPROVAL

I hereby certify that this proposal has been reviewed and approved by this Office/Bureau. Our review finds that the research is ethically appropriate, does not unduly disrupt the organization/agency/program, and is compatible with the agency's research agenda; i.e., it will benefit the patient and/or service delivery system.

(Obtain appropriate signatures for Offices or BHSF).

_____

Regional Manager Date

(for region-based projects)

_____

Division Director Date

(for region-based/program-based projects)

_____

Assistant Secretary or Director of BHSF Date

(for statewide projects)

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